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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,941	03/24/2004	Yoram Rudy	CWO-002.02	5129

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Yoram Rudy
3030 Huntington Road
Shaker Heights, OH 44120

EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	PAPER NUMBER
3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,941	RUDY, YORAM	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to a heart probe.

Group II, claim(s) 7-12, drawn to a method of measuring electrical potentials.

Group III, claim(s) 13-15, drawn to a system for determining electrical potentials.

Group IV, claim(s) 16-18, drawn to a method of determining electrical potentials.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I does not require positioning the probe for non-contact or measuring electrical potentials but could be used for contact and delivering stimulation. Group II does not require imaging means or determining a geometric relationship between the probe and endocardial surface but can be used by measuring impedance values to determine location. Group III does not require a terminal end spiral shape or non-contact, but could be straight and be contacting the heart. Group IV does not require a terminal end spiral shape or imaging means, but could have a straight terminal end and use impedance values to determine location.

During a telephone conversation with Richard Sutkus on 12/21/06 a provisional election was made without traverse to prosecute the invention of group I, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statement filed 10/8/04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because one reference does not include a date of publication. It has been placed in the application file, but the information referred to therein for that one reference has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "and positioned for non-contact" is vague and sounds like a method step rather than a structural limitation. It is suggested to use "and adapted for ...". In addition, "where the probe is inserted percutaneously" sounds more like a method step (and product by process step) than a structural limitation. It is suggested to use "wherein said probe is adapted to be inserted percutaneously".

In claim 4, "at least one of" is vague since it is unclear how it could be both a pigtail and helix shape. It is suggested to delete "at least".

In claim 5, the claim is vague since it sounds like a method step rather than a structural limitation. The claims are only directed to the probe and not to any other element to reconstruct potentials. It is suggested to state "wherein said probe is adapted to provide...".

In claim 6, the claim is vague for sounding like a method step and does not further limit the probe since it is not directed to the probe but the reconstruction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Beatty et al (6240307). Beatty discloses a non-contact probe (e.g. column 2, line 62) that has a terminal end (considered to be from the expanded array to the very distal tip/end) shaped in a spiral/pigtail/helix and generally cylindrical shape (figures 2-5, e.g. col 3-5) and uses a means to conform the terminal end into a spiral shape as the stylet (or balloon) to conform the end into a spiral shape (e.g. col 3-5) since a person of ordinary skill in the art would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification and since the prior art element is a structural equivalent of the corresponding

element disclosed in the specification since both provide and implantable way to quickly and easily bend the catheter into the desired shape once in the heart cavity. In addition, Beatty's probe is capable of reconstruction of endocardial potentials on the endocardial surface and on a beat by beat basis since it provides the cardiac signals to the electrical connectors for processing. It is noted that claims 5 and 6 do not claim the actual system for beat by beat potentials, just that the probe is capable of providing them.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Giba et al (5997526). Giba discloses a probe that has a terminal end shaped in a spiral/pigtail/helix and generally cylindrical shape (e.g. figures 2a, 2b, 5b, and 6) and uses a means to conform the terminal end into a spiral shape as the heating of the probe to conform the end into a spiral shape (e.g. col 3-5) since a person of ordinary skill in the art would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification and since the prior art element is a structural equivalent of the corresponding element disclosed in the specification since both provide and implantable way to quickly and easily bend the catheter into the desired shape once in the heart cavity. It is noted that the right hand side of figure 6 shows the probe in a non-contact position and Giba is also capable of meeting the functional use recitations in the claim of being a non-contact probe since his probe does not need to contact the endocardial surface, the shape of the probe can be controlled to be non-contact, and since the size of the patients heart is a relative size and the probe of Giba could be used in a larger sized heart. Giba's probe is capable of reconstruction of endocardial potentials on the endocardial surface and on a beat by beat basis since it provides the cardiac

signals to the electrical connectors for processing. It is noted that claims 5 and 6 do not claim the actual system for beat by beat potentials, just that the probe is capable of providing them.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kagan et al (5311866). Kagan discloses a non-contact probe (e.g. column 2) that has a terminal end (considered to be from the expanded array to the very distal tip/end) shaped in a spiral/pigtail/helix and generally cylindrical shape (e.g. figures 2-5) and uses a means to conform the terminal end into a spiral shape as the stylet to conform the end into a spiral shape (e.g. col 3-4) since a person of ordinary skill in the art would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification and since the prior art element is a structural equivalent of the corresponding element disclosed in the specification since both provide and implantable way to quickly and easily bend the catheter into the desired shape once in the heart cavity. In addition, Kagan's probe is capable of reconstruction of endocardial potentials on the endocardial surface and on a beat by beat basis since it provides the cardiac signals to the electrical connectors for processing. It is noted that claims 5 and 6 do not claim the actual system for beat by beat potentials, just that the probe is capable of providing them.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Imran (5239999). Imran discloses a probe that has a terminal end shaped in a spiral/pigtail/helix and generally cylindrical shape (e.g. figures 16 and 19) and uses a means to conform the terminal end into a spiral shape as the torque element or wire (e.g. col 13, line 26) since a person of ordinary skill in the art would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification and since the prior art element is a structural

equivalent of the corresponding element disclosed in the specification since both provide and implantable way to quickly and easily bend the catheter into the desired shape once in the heart cavity. It is noted that Imran is also capable of meeting the functional use recitations in the claim of being a non-contact probe since his probe does not need to contact the endocardial surface, the shape of the probe can be controlled to be non-contact, and since the size of the patients heart is a relative size and the probe of Imran could be used in a larger sized heart. Imran's probe is capable of reconstruction of endocardial potentials on the endocardial surface and on a beat by beat basis since it provides the cardiac signals to the electrical connectors for processing. It is noted that claims 5 and 6 do not claim the actual system for beat by beat potentials, just that the probe is capable of providing them.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6839588. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are narrower and meet the limitations of the broader application claims. In addition, it would have been obvious to one having ordinary skill in the art to include in the patented claims the use of the probe being adapted to be inserted percutaneously since it was known in the art that mapping probes are adapted to be inserted percutaneously to allow the probe to be placed in the body for a minimal amount of time to diagnose heart conditions and removed upon analysis/correction of the heart condition so as to not affect the patient over a long period of time.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762

12/24/06

GRE
December 24, 2006